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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,114	11/22/2000	Hirohiko Hirochika	MAFF-1	2997

1473 7590 10/03/2003

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/721,114	HIROCHIKA ET AL.
	Examiner	Art Unit
	Juliet C. Switzer	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 5/21/03. Claims 4-11 were cancelled. Claim 1 remains pending and is examined herein. Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is final.**

Claim Rejections - 35 USC § 101

2. Claim1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

Claim 1 is drawn to a polynucleotide encoding polypeptide involved in a signal transduction system for brassinosteroid hormone, said polypeptide consisting of the amino acid sequence from Met at position 1 to Arg at position 1057 of SEQ ID NO: 2. The specification asserts that these polynucleotides are of use in plant breeding (p. 14). Specifically, the specification teaches that "by introducing the present polynucleotide into plants and artificially controlling various effects in which the brassinosteroid hormone is involved, it is expected that effects such as growth promotion, yield increase, quality improvement, maturation enhancement, and tolerance against biotic and abiotic stresses can be controlled... (p. 14)." However, beyond this assertion, the specification does not provide any guidance or evidence that such effects can be achieved in plants.

The specification demonstrates in two different strains of rice that the disruption of the expression of instant SEQ ID NO: 2 causes dwarfism in plants (see examples 2 and 3). The specification further demonstrates that in wild type plants SEQ ID NO: 2 is expressed in a variety of different plant tissues (see example 4). The specification further teaches that there are putative nuclear localization signals and ATP/GTP binding domains in the polypeptide encoded by instant SEQ ID NO: 2 (see example 5). Finally, the specification demonstrates that while normal plant leaves bend in response to treatment with brassinolide, the mutant plants with disrupted SEQ ID NO: 2 do not respond to the treatment (see example 6). Thus, it is reasonable to conclude that the polypeptide encoded by instant SEQ ID NO: 2 has some functionality in the response of rice plants to brassinolide. Nonetheless, the determination that a polypeptide is part of a particular pathway does not equate to the provision of a specific, substantial and credible utility.

Altmann provides a review of advances in brassinosteroid molecular genetics (Current Opinion in Plant Biology, 1998, Vol. 1, pages 378-783). Altmann teaches that mutant plants that are insensitive to brassinosteroids may be blocked in the primary perception of the BR signal, in essential components of the signal transduction pathway, or in the target genes that are responsible for the major components of the response (p. 781, second column). Thus, the instant polypeptides "involvement" in the signaling transduction for brassinosteriod hormone may be at any number of positions in a complicated pathway. Functionality in any one of these capacities would have an effect on how and when the instant polynucleotides would be useful.

In order to utilized the instant invention, further experimentation would be necessary to reasonably confirm the activity of the claimed polynucleotides and how they can be used to

effect the goals postulated by applicant. In genetically modified plants, the introduced transgenes are sometimes not expressed, and they can also result in co-suppression effects. None of these effects are predictable, and the mechanisms of gene silencing are still not fully understood. Thus, success in modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. Moreover, the phenotypic characteristics that will result from expression of a given DNA construct cannot be reliably predicted. In fact, often the expected phenotypic result is not achieved. Thus, in light of the instant disclosure, the proposed utility is not considered to be substantial because further experimentation would be necessary to reasonably confirm a use for the claimed polynucleotides.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be

required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Response to Remarks

In response to the 101 utility rejection and the 112 1st paragraph lack of enablement rejection, applicant traverses the examiner's assertion that the specification does not provide evidence of a causative relationship between the presence of the mutated form of the claimed polynucleotide and an altered response to brassinosteroid hormone. This concern raised by the examiner is withdrawn in view of a careful review of the examples and arguments, and applicant's amendment to the claim. As noted in the revised rejection, it is reasonable to conclude based on the evidence of record that the polypeptide encoded by instant SEQ ID NO: 2 has some functionality in the response of rice plants to brassinolide. However, this is not sufficient to provide a substantial or specific utility for the claimed invention.

Applicant reiterates in the remarks filed 5/21/03 on pages 3-4 that applicants have demonstrated that disruption of the expression of the polypeptide recited in claim 1 results in dwarf plants (Examples 2 and 3) , that the corresponding gene is expressed in a variety of plant tissues (Example 4) and lack of response in strains with a mutation in the gene to a brassinosteroid hormone. These points are not disputed. However, neither do these showings establish a specific and substantial utility for the claimed invention because it is not clear, even in view of these observations, what one would actually use the claimed nucleic acid to accomplish.

Applicants argue that they need not further demonstrate how the polypeptide affects any particular pathway or phenotype, and states that the fact that the polypeptide does have an affect on response to brassinosteroid hormone and that lack of expression of the polypeptide result sin dwarf plants satisfies the requirement of 35 USC 101, however, applicant does not support this assertion with reasoning. Applicant, does not set forth what the polypeptide can actually be used for. The specification "by introducing the present polynucleotide into plants and artificially controlling various effects in which the brassinosteroid hormone is involved, it is expected that effects such as growth promotion, yield increase, quality improvement, maturation enhancement, and tolerance against biotic and abiotic stresses can be controlled... (p. 14)." Applicant states in the response that because it is known that the polypeptide interrupts brassinosteroid response and causes dwarfism the polynucleotide is useful. But the specification does not reasonably confirm that polynucleotide is useful to actually manipulate any aspect of the complicated brassinosteriod pathway, either for growth enhancement as suggested in the specification or to create dwarf plants.

The creation of dwarf plants via cosuppression as discussed on pages 4-5 of the instant specification is not an asserted utility in the specification. Applicant's first mention of this utility is in the instantly filed arguments. Further, though methods of using cosuppression were known at the time the invention was made, the specification does not provide any demonstration that such effects could be achieved using the nucleic acid disclosed in claim 1. And while one could screen plants to identify one or more with a desired phenotypic trait, such as dwarfing, it remains highly unpredictable that such an effect could be achieved using the claimed nucleic acid in the first place. The effects of manipulating the expression of the claimed polynucleotide on plants is

highly unpredictable as the polynucleotide is part of a complicated pathway, and expression of the polynucleotide has been observed throughout the entire plant. As with the utilities asserted in the specification, further experimentation would be required to reasonably confirm even this utility.

Thus, for these reasons and all of the reasons of record the rejection for lack of utility is maintained.

Conclusion

3. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

Juliet C Switzer
Patent Examiner
AU 1634

September 29, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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